

Exhibit 4

Federal Court



Cour fédérale

Appendix "4" to the Order dated November 25, 2019

Court File Nos.: T-704-19

T-705-19

T-708-19

FEDERAL COURT

BETWEEN:

**HOFFMANN-LA ROCHE LIMITED
AND INTERMUNE, INC.**

Plaintiffs

and

SANDOZ CANADA INC.

Defendant



LETTER OF REQUEST

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LETTER OF REQUEST

TO THE JUDICIAL AUTHORITIES OF: The United States District Court for the District of New Jersey

A PROCEEDING IS PENDING IN THE FEDERAL COURT between the Plaintiffs, Hoffmann-La Roche Limited located at 7070 Mississauga Road, Mississauga, Ontario, L5N 5M8, Canada and InterMune, Inc. located at c/o Genentech, Inc., Legal Department, 1 DNA Way, South San Francisco, California, 94080-4990, United States of America (collectively, “Roche”); and the Defendant, Sandoz Canada Inc., located at 110 de Lauzon, Boucherville, Québec, J4B 1E6, Canada (“Sandoz”). Legal counsel for the Plaintiffs are Yoon Kang, Nancy Pei, Y. Lynn Ing, and Brandon Heard at SMART & BIGGAR LLP, 1100-150 York Street, Toronto, Ontario, M5H 3S5, Canada. Legal counsel for the Defendant are Warren Sprigings and Mingquan Zhang at Sprigings Intellectual Property Law, 148 Norseman Street, Toronto, Ontario, M8Z 2R4, Canada. The proceeding relates generally to the following:

1. These actions were commenced by the Plaintiffs regarding the patents in issue in this letter of request: Canadian Patent Nos. 2,620,380 (the “380 Patent”) and 2,762,013 (the “013 Patent”) (collectively, the “Patents in Issue”). The ‘013 Patent was issued from a divisional application based on the application for the ‘380 Patent. Roche is seeking, *inter alia*, declarations that the asserted claims of the respective patents would be infringed by Sandoz.

2. Sandoz served Statements of Defence in the same proceedings on the basis, *inter alia*, that: (1) the asserted claims of the Patents in Issue are invalid; and (2) the Sandoz proposed product would not infringe the asserted claims of the Patents in Issue.

3. Each of the Patents in Issue names three inventors: Ramachandran Radhakrishnan, Ronald Vladyka, and Kenneth Sultzbaugh. Roche has agreed to make Ramachandran Radhakrishnan and Kenneth Sultzbaugh available for examination for discovery. To date, Ronald Vladyka has not agreed to voluntarily attend the examination for discovery.

4. The trial for the proceedings for the Patents in Issue is scheduled to commence on January 11, 2021 in Toronto, Ontario, Canada. There is a scheduling order in these proceedings which requires Sandoz to serve its expert reports on validity by August 7, 2020. While the Plaintiffs do not accept that Ronald Vladyka necessarily has relevant knowledge or documents, the information sought to be obtained by Sandoz from Ronald Vladyka relates to his role in the development of the subject-matter claimed in the Patents in Issue which may be relevant to the validity issues under the laws of Canada.

5. The allegations in the proceedings include, *inter alia*, the following:

(1) The '380 Patent purportedly describes the following subject-matter:

6. "The present disclosure relates in general to pirfenidone, a small drug molecule whose chemical name is 5-methyl-1-phenyl-2-(1H)-pyridone. Specifically, the present disclosure relates to a capsule formulation of pirfenidone including pharmaceutically acceptable excipients. Further provided are methods of using such capsule formulation in the treatment of fibrotic conditions and other disorders mediated by cytokines." ('380 Patent, p. 1).

(2) Claim 1 of the '380 Patent reads as follows:

7. “1. A capsule dosage form comprising a capsule shell having disposed therein a pharmaceutical formulation of 5-methyl-1-phenyl-2-(1H)-pyridone, wherein said pharmaceutical formulation comprises 5-30% by weight of pharmaceutically acceptable excipients and 70-95% by weight of 5-methyl-1-phenyl-2-(1H)-pyridone, wherein said excipients comprise an effective amount of a binder that interacts with the amide carbonyl group of 5-methyl-1-phenyl-2-(1H)-pyridone to increase the AUC of 5-methyl-1-phenyl-2-(1H)-pyridone upon oral administration, as compared to a capsule of 5-methyl-1-phenyl-2-(1H)-pyridone comprising no excipients.”

- (3) Sandoz has alleged that the asserted claims of the ‘380 Patent are anticipated by prior art, obvious to a skilled person, constitute double patenting, are insufficiently disclosed, lack utility and sound prediction, are broader than the purported invention made or disclosed and are ambiguous.

- (4) The ‘013 Patent, purportedly describes the following subject-matter:

8. “The present disclosure relates in general to pirfenidone, a small drug molecule whose chemical name is 5-methyl-1-phenyl-2(1H)-pyridone. Specifically, the present disclosure relates to a granulation of pirfenidone including pharmaceutically acceptable excipients. Further provided is use of such granulation in the treatment of fibrotic conditions and other disorders mediated by cytokines.” (‘013 Patent, p. 1).

- (5) Claim 1 of the ‘013 Patent reads as follows:

9. “1. A granulation of 5-methyl-1-phenyl-2-(1H)-pyridone, wherein said granulation comprises pharmaceutically acceptable excipients and 5-methyl-1-phenyl-2-(1H)-pyridone, wherein said excipients comprise an effective amount of a binder that interacts with the amide carbonyl group of 5-methyl-1-phenyl-2-(1H)-pyridone to increase the AUC of pirfenidone at least 45% upon oral administration, as compared to 5-methyl-1-phenyl-2-(1H)-pyridone comprising no excipients orally administered in a capsule shell.”

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- (6) Sandoz has alleged that the asserted claims of the '013 Patent are anticipated by prior art, obvious to a skilled person, constitute double patenting, are insufficiently disclosed, lack utility and sound prediction, are broader than the purported invention made or disclosed, and are ambiguous.

IT HAS BEEN SHOWN TO THIS COURT that it appears necessary for the purpose of justice that witnesses residing in your jurisdiction be examined there.

THIS COURT HAS ISSUED A COMMISSION (also known as, "LETTER ROGATORY") to a Commissioner to be named by the Presiding Judge of the United States District Court for the District of New Jersey, providing for the examination of the witness, Ronald Vladyka, residing at 15 Norfolk Road, Somerset, New Jersey, 08873, U.S.A.

YOU ARE REQUESTED, in furtherance of justice, to cause Ronald Vladyka to appear before the Commissioner by the means ordinarily used in your jurisdiction, and, if necessary, to secure attendance, and to answer questions under oath or affirmation and to bring to and produce at the examination the following documents and things in his possession, power or control:

1. Ronald Vladyka's up-do-date *curriculum vitae* (or résumé);
2. copies of any affidavits or declarations that have been sworn by Ronald Vladyka in any matter relating to the subject-matter of the '380 and '013 Patents, or corresponding foreign patents and applications, including United States Patent Nos. US 7,767,225, US 7,988,994, US 8,383,150, US 8,753,679

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and Application Publication No. US 2014/242159 and European Patent No. EP 1,940,364 and Application EP 2,431,025; and

3. copies of documents (including laboratory notebook pages, notes, memoranda, reports, data, correspondence, emails, computer files, and notes of any discussions) relating to the formulations and clinical studies described in the '380 and '013 Patents.

YOU ARE ALSO REQUESTED to permit the Commissioner to conduct the examination of the witness with the assistance of counsel for Roche and Sandoz, and on notice to and with the attendance of counsel for Roche and Sandoz, in accordance with the *Federal Courts Rules* and the Commission issued by this Court under the following parameters:

1. Ronald Vladyka is to attend in or near Somerset, New Jersey in a place mutually determined by the parties or as determined by the United States District Court for the District of New Jersey and be examined for discovery before the Commissioner. It is anticipated that one day will be required for Ronald Vladyka to answer questions on the areas set out below as related to the '380 and '013 Patents:
 - a. background and experience, including pharmaceutical formulation and clinical trials;
 - b. preparation of pirfenidone formulations containing a binder;
 - c. administration of pirfenidone formulations containing a binder in humans, and collection and analysis of pharmacokinetic parameters;

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- d. use of pirfenidone for treating idiopathic pulmonary fibrosis;
 - e. administration of capsules of pirfenidone comprising no excipients in humans, and collection and analysis of pharmacokinetic parameters;
 - f. physical and chemical characterization of any interaction between pirfenidone and excipients;
 - g. study on the impact of the interaction between pirfenidone and excipients, if any, on pharmacokinetic parameters.
2. Sandoz shall directly pay the costs of the court reporter or stenographer at the examination of Ronald Vladyka.
3. Costs incurred by the judicial authorities of the United States District Court for the District of New Jersey in executing the Letter of Request shall be reimbursed directly by Sandoz.
4. The examination of Ronald Vladyka is to be scheduled and taken as soon as practically possible following the issuance of the Commission and Letter of Request, but no earlier than January 19, 2020 in order to assist with the proceedings, where the trial is scheduled to commence on January 11, 2021.
5. The executed Letter of Request may be returned to Counsel for Sandoz.

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AND WHEN YOU REQUEST IT, the Federal Court is ready and willing to do the same for you in a similar case.

THIS LETTER OF REQUEST is signed and sealed by order of the Court made on NOV 25 2019 (date).

Date:

NOV 25 2019

Issued by:

PAUL SCHUTZ
REGISTRY OFFICER
AGENT DU GREFFER

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